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PATENT  
1653

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

(Case No. 98-009-B1)

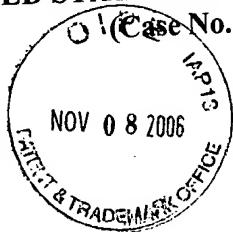
In application of:

Rogers, et al.

Serial No. 09/658,315

Filed: September 8, 2000

For: Method of Promoting Erythropoiesis



Examiner : A. Gupta

Group Art Unit: 1653

Confirmation No.: 3507

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

In regard to the above identified application:

1. We are transmitting herewith the attached:

- Transmittal letter (1 sheet);
- Information Disclosures Statement (IDS) in compliance with the continuing duty of candor as set forth in 37 C.F.R. § 1.56 And IDS Form 1449 (12 sheets);
- Supplemental Information Disclosure Statement (IDS) and IDS Form 1449 Form (5 sheets);
- Copy of International Search Report from corresponding PCT Patent App. Serial No. PCT/US99/02648 (publication no. WO99-40106) (5 sheets);
- Return Receipt Postcard

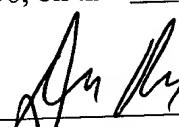
2. With respect to fees:

- Enclosed please find a check in the amount of \$180.00 for the IDS Fee.

3. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2490.

4. CERTIFICATE OF MAILING BY "EXPRESS MAIL" UNDER 37 CFR § 1.10: The undersigned hereby certifies that this Transmittal Letter and the papers, as described hereinabove, are being deposited with the United States Postal Service with sufficient postage as "Express Mail Post Office to Addressee" in a box addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 8<sup>th</sup> day of November, 2006. Express Mail No. EV839376871US.

By:

  
\_\_\_\_\_  
David Harper  
Reg. No. 42,636



PATENT

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**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents and Trademarks  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. Section 1.97 - 1.99, the Applicant wishes to make the following references of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56. Pursuant to 37 C.F.R. §1.98(d), copies of references numbered 1-57 are not provided herewith, since they were previously filed in the parent U.S. application serial no. 09/245,680.

Applicants do not believe any fee is due with this submission. If this belief be in error and the Patent Office determines that the fee prescribed in the relevant portion of 37 C.F.R. Section 1.97 is applicable, the undersigned attorney by his signature hereby authorizes any such fee to be debited from Deposit Account 13-2490.

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THIS INFORMATION DISCLOSURE STATEMENT IS BEING FILED:

- within three months of the filing date of a national application; within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 in an international application; or before the mailing date of a first Office Action on the merits. 37 C.F.R. §1.97 (b)
- after three months of the filing date of a national application, or the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 in an international application; or after the mailing date of a first Office Action on the merits, but before the mailing date of a Final Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311 (whichever occurs first), and includes (37 C.F.R. § 1.97 (c):
  - the Certification under 37 C.F.R. § 1.97(e) (see “Certification” below)

**OR**

- the fee of \$180 set forth in 37 C.F.R. § 1.17(p) (see “Fees” below).
- after a Final Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311 (whichever occurs first), but before, or simultaneously with, the payment of the issue fee, and includes the Certification under 37 C.F.R. § 1.97(e) (see “Certification” below), and the Petition Fee set forth in 37 C.F.R. § 1.17(i) (see “Fees” and “Method of Payment of Fees” below). Applicants hereby petitions for consideration of the Information Disclosure Statement submitted herewith and the accompanying references in examination of the subject patent application.

CERTIFICATION

- The **undersigned** hereby certifies that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- The **undersigned** hereby certifies that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

FEES

No fee is owed by the applicant(s).  
 The IDS Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.  
 The Petition Fee of \$130.00 set forth in 37 C.F.R. § 1.17(i) is enclosed herewith.

METHOD OF PAYMENT OF FEES

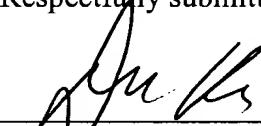
Attached is a check in the amount of \$180.00.  
 Charge Deposit Account No. 13-2490 in the amount of \$ . (A duplicate copy of this communication is enclosed for that purpose.)

Please charge any underpayment or credit any overpayment in connection with this communication to Deposit Account No. 13-2490. A duplicate copy of this communication is enclosed for this purpose.

**CERTIFICATE OF MAILING AS "EXPRESS MAIL" (37 CFR 1.10)** I hereby certify that this correspondence and all attached paper(s) or fee(s) is being deposited with sufficient postage, with the United States Postal Service as EXPRESS MAIL POST OFFICE TO ADDRESSEE in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 with sufficient postage, on this 8 Day of November, 2006. under Express Mail Certificate No. EV839376871US.

Date: 11/8/06

Respectfully submitted,

  
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David S. Harper  
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**McDonnell Boehnen Hulbert & Berghoff**  
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#### U.S. Patent Documents:

- 1.) Rodgers, et al., U.S. Patent No. 5,834,432, Issued: November 10, 1998.
- 2.) Rodgers, et al., U.S. Patent No. 5,955,430, Issued: September 21, 1999.
- 3.) Baertschi, et al., U.S. Patent No. 4,987,121, Issued: January 22, 1991.
- 4.) Royet, et al., U.S. Patent No. 5,482,924, Issued: January 9, 1996.
- 5.) diZerega, et al., U.S. Patent No. 5,015,629, Issued: May 14, 1991.
- 6.) Rodgers, et al., U.S. Patent No. 5,629,292, Issued: May 13, 1997.
- 7.) Rodgers, et al., U.S. Patent No. 5,716,935, Issued: February 10, 1998.
- 8.) Krstenansky, et al., U.S. Patent No. 5,693,616, Issued: December 2, 1997.
- 9.) Goldberg, et al., U.S. Patent No. 5,188,828, Issued: February 23, 1993.
- 10.) Vance, et al., U.S. Patent No. 5,541,158, Issued: July 30, 1996.
- 11.) Yu, et al., U.S. Patent No. 5,032,507, Issued: July 16, 1991.
- 12.) Michalevicz, et al., U.S. Patent No. 5,104,653, Issued: April 14, 1992.

#### Foreign Documents:

- 13.) International Published Application No. WO 96/39164, Published: December 12, 1996.
- 14.) International Published Application No. WO 95/08565, Published: March 30, 1995.
- 15.) International Published Application No. WO 95/08337, Published: March 30, 1995.

### Article References:

- 16.) Kurt R. Reissmann, M.D., (1950), *Blood*, "Studies on the Mechanism of Erythropoietic Stimulation in Parabiotic Rats During Hypoxia", 8: pp. 349-357.
- 17.) Allan Erslev, M.D., (1953), *Blood*, "Humoral Regulation of Red Cell Production", 8: pp. 349-357.
- 18.) Jerry L. Spivak, (1986), *Int. J. Cell Cloning*, "The Mechanism of Action of Erythropoietin", 4: pp. 139-166.
- 19.) K. Sawada, et al., (1987), *The Journal of Clinical Investigation, Inc.*, "Purification of Human Erythroid Colony-forming Units and Demonstration of Specific Binding of Erythropoietin", 80: pp 357-366.
- 20.) T.S. Kickler, et al., (1988), *J. Am. Med. Assoc.*, "Effect of Repeated Whole Blood Donations on Serum Immunoreactive Erythropoietin Levels in Autologous Donors", 260: pp. 65-67.
- 21.) Jaime Caro, et al., (1979), *J. Lab. Clin. Med.*, "Erythropoietin Levels in Uremic Nephric and Anephric Patients", 93: pp. 449-458.
- 22.) Heinz W. Radtke, et al., (1979), *Blood*, "Serum Erythropoietin Concentration in Chronic Renal Failure: Relationship to Degree of Anemia and Excretory Renal Function" 54(4): pp. 877-884.
- 23.) Manju Chandra, M.D., et al., (1988), *J. Pediatr.*, "Relation of Serum Erythropoietin Levels to Renal Excretory Function: Evidence for Lowered Set Point for Erythropoietin Production in Chronic Renal Failure", 113: pp. 1015-1021.
- 24.) Joseph W. Eschbach, M.D., et al., (1988), *American Journal of Kidney Diseases, Recombinant Human Erythropoietin: Implications for Nephrology* 11: pp. 203-209.
- 25.) Satya P. Kunapuli, et al., (1987), *Circulation Research*, "Molecular Cloning of Human Angiotensinogen cDNA and Evidence for the Presence of Its mRNA in Rat Heart" 60: pp. 786-790.
- 26.) W.M. Clouston, et al., (1988), *Genomics*, "Molecular Cloning of the Mouse Angiotensinogen Gene", 2: pp. 240-248.
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34.) B.I. Shand, et al., (1995), *Journal of Human Hypertension*, "Effect of Losartan on Haematology and Haemorheology in Elderly Patients with Essential Hypertension: A Pilot Study", 9: pp. 233-235.

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39.) Michal Mrug, et al., (1997), *The American Society for Clinical Investigation, Inc.*, "Angiotensin II Stimulates Proliferation of Normal Early Erythroid Progenitors", 100(9): pp. 2310-2314.

40.) Fisher, et al., (1968), *Annals New York Academy of Sciences*, "Effects of Angiotensin, Norepinephrine and Renal Artery Constriction on Erythropoietin Production", pp. 308-317.

41.) James W. Fisher, et al., (1967), *The Journal of Pharmacology and Experimental Therapeutics*, "Effects of Angiotensin and Renal Artery Constriction on Erythropoietin Production", 157(3): pp. 618-625.

42.) D.L. Mann, et al., (1966), *P.S.E.B.M.*, "Effect of Renin, Angiotensin II and Aldosterone on Erythropoiesis", 121: pp. 1152-1154.

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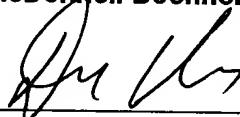
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Date:

11/8/06

By:

Respectfully submitted,  
**McDonnell Boehnen Hulbert & Berghoff LLP**

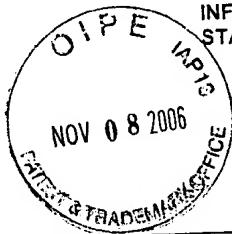


David S. Harper  
Registration No. 42,636

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Patent and Trademark Office

Atty. Docket No.

Serial No.  
09 / 658 , 315INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

Applicant: Kathleen Rodgers, et al.

Filing Date: Sept 8, 2000

Group: 1653

## U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date
	1.	5,834,432	11-10-98	Rodgers, et al.			
	2.	5,955,430	9-21-99	Rodgers, et al.			
	3.	4,987,121	1-22-91	Baertschi, et al.			
	4.	5,482,924	1-9-96	Royer, et al.			
	5.	5,015,629	5-14-91	diZerega, et al.			
	6.	5,629,292	5-13-97	Rodgers, et al.			
	7.	5,716,935	2-10-98	Rodgers, et al.			
	8.	5,693,616	12-2-97	Krstenansky, et al.			
	9.	5,188,828	2-23-93	Goldberg, et al.			
	10.	5,541,158	7-30-93	Vance, et al.			
	11.	5,032,507	7-16-91	Yu, et al.			
	12.	5,104,653	4-14-92	Michalevitz, et al.			

## FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes No
	13	WO 96/39164	12-12-96	PCT			X
	14.	WO 95/08565	3-30-95	PCT			X
	15.	WO 95/08337	3-30-95	PCT			X

## OTHER DOCUMENTS - Including Author, Title, Date, Pertinent Pages, Etc.

16.	Kurt R. Reissmann, M.D., (1950), <i>Blood</i> , "Studies on the Mechanism of Erythropoietic Stimulation in Parabiotic Rats During Hypoxia", 8: pp. 349-357.
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35.	Bruce A. Julian, et al., (1994), <i>Kidney International</i> , "Erythropoiesis After Withdrawal of Enalapril in Post-Transplant Erythrocytosis", 46: pp. 1397-1403.
36.	R.S. Gaston, et al., (1993), <i>Transplantation Proceedings</i> , "Enalapril: Safe and Effective Therapy for Posttransplant Erythrocytosis", 25(1): pp. 1029-1031.

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42.	D.L. Mann, et al., (1966), <i>P.S.E.B.M.</i> , "Effect of Renin, Angiotensin II and Aldosterone on Erythropoiesis", 121: pp. 1152-1154.
43.	Yilmaz C. Bilsel, et al., (1963), <i>P.S.E.B.M.</i> "Angiotensin II and Erythropoiesis", 114: pp. 475-479.
44.	Ferrario, et al., (1998), <i>J. Am. Soc. Nephrol.</i> , "Novel Angiotensin Peptides Regulate Blood Pressure, Endothelial Function, and Natriuresis", 9: pp. 1716-1722.
45.	Shridhar N. Iyer, et al., (1998), <i>Hypertension</i> , "Vasodepressor Actions of Angiotensin-(1-7) Unmasked During Combined Treatment with Lisinopril and Losartan", 31: pp. 699-705.
46.	Freeman, et al., (1996), <i>Hypertension</i> , "Angiotensin-(1-7) Inhibits Vascular Smooth Muscle Cell Growth", 28: page 104-108.
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53.	Richard M. Edwards, et al., (1993), <i>The Journal of Pharmacology and Experimental Therapeutics</i> , "Angiotensin II Inhibits Glomerular Adenylate Cyclase via the Angiotensin II Receptor Subtype I (AT <sub>1</sub> )", 266(2): pp. 506-510.
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Examiner	Date Considered
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with any communication.

Form PTO-1449	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 98,009-B1	Serial No. 09 / 658 , 315
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Applicant: Kathleen Rodgers, et al.	
		Filing Date: Sept 8, 2000	Group: 1653

## OTHER DOCUMENTS - Including Author, Title, Date, Pertinent Pages, Etc.

55.	Neelam Jaiswal, et al., (1991), <i>Hypertension</i> , "Subtype 2 Angiotensin Receptors Mediate Prostaglandin Synthesis in Human Astrocytes", 17: pp. 1115-1120.
56.	Ilkka Pörsti, et al., (1994), <i>Br. J. Pharmacol.</i> , "Release of Nitric Oxide by Angiotensin-(1-7) from Porcine Coronary Endothelium: Implications for a Novel Angiotensin Receptor", 111: pp. 652-654.
57.	Regoli, et al., (1974), <i>Pharmacological Reviews</i> , "Pharmacology of Angiotensin I", 26(2): pp. 69-123.
Examiner	Date Considered

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with any communication.



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Case No. 98-009-B1)

In application of:

Rogers, et al.

Serial No. 09/658,315

Filed: September 8, 2000

For: Method of Promoting Erythropoiesis

Examiner : A. Gupta

Group Art Unit: 1653

Confirmation No.: 3507

SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents and Trademarks  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. Section 1.97 - 1.99, the Applicant wishes to make the following references of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56. Pursuant to 37 C.F.R. §1.98(d), copies of references numbered 1-4 are not provided herewith, since they were previously filed in the parent U.S. application serial no. 09/245,680.

Applicants do not believe any fee is due with this submission. If this belief be in error and the Patent Office determines that the fee prescribed in the relevant portion of 37 C.F.R. Section 1.97 is applicable, the undersigned attorney by his signature hereby authorizes any such fee to be debited from Deposit Account 13-2490.

THIS INFORMATION DISCLOSURE STATEMENT IS BEING FILED:

- within three months of the filing date of a national application; within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 in an international application; or before the mailing date of a first Office Action on the merits. 37 C.F.R. §1.97 (b)
- after** three months of the filing date of a national application, or the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 in an international application; or **after** the mailing date of a first Office Action on the merits, but **before** the mailing date of a Final Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311 (whichever occurs first), and includes (37 C.F.R. § 1.97 (c):
  - the Certification under 37 C.F.R. § 1.97(e) (see "Certification" below)

**OR**

- the fee of \$180 set forth in 37 C.F.R. § 1.17(p) (see "Fees" below).
- after** a Final Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311 (whichever occurs first), but before, or simultaneously with, the payment of the issue fee, and includes the Certification under 37 C.F.R. § 1.97(e) (see "Certification" below), and the Petition Fee set forth in 37 C.F.R. § 1.17(i) (see "Fees" and "Method of Payment of Fees" below). Applicants hereby petitions for consideration of the Information Disclosure Statement submitted herewith and the accompanying references in examination of the subject patent application.

CERTIFICATION

- The **undersigned** hereby certifies that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- The **undersigned** hereby certifies that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

FEES

**No fee** is owed by the applicant(s).  
 The **IDS Fee of \$180.00** under 37 C.F.R. § 1.17(p) is enclosed herewith.  
 The **Petition Fee of \$130.00** set forth in 37 C.F.R. § 1.17(i) is enclosed herewith.

METHOD OF PAYMENT OF FEES

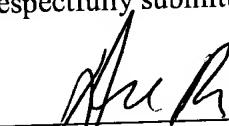
Attached is a check in the amount of \$180.00.  
 Charge Deposit Account No. 13-2490 in the amount of \$ . (A duplicate copy of this communication is enclosed for that purpose.)

Please charge any underpayment or credit any overpayment in connection with this communication to Deposit Account No. 13-2490. A duplicate copy of this communication is enclosed for this purpose.

**CERTIFICATE OF MAILING AS "EXPRESS MAIL" (37 CFR 1.10)** I hereby certify that this correspondence and all attached paper(s) or fee(s) is being deposited with sufficient postage, with the United States Postal Service as EXPRESS MAIL POST OFFICE TO ADDRESSEE in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 with sufficient postage, on this 8<sup>th</sup> Day of November, 2006. under Express Mail Certificate No. **EV839376871US**.

Respectfully submitted,

Date: 11/8/06

  
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**FOREIGN PATENT DOCUMENTS:**

1. PCT Published Patent Application No. WO 98-32457, Published on July 30, 1998.
2. PCT Published Patent Application No. WO 99-31125, Published on June 24, 1999.
3. PCT Published Patent Application No. WO 99-26644, Published on June 3, 1999.

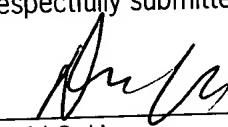
**ARTICLE REFERENCES:**

4. Mrug, et al., (1996), "Angiotensin II Facilitates Erythropoietin-mediated proliferation of early erythroid progenitors", Vol: 88, page 646a.

Respectfully submitted,

Date: 11/8/06

By:

  
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Registration No. 42,636

FORM PTO-1449  
(Rev. 2-32)

U.S. Department of Commerce  
Patent and Trademark Office

Atty. Docket No.

98-009-B1

Serial No.

09/658,315



SUPPLEMENTAL  
INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)

Applicant:

Rogers, et al.

Filing Date:

September 8, 2000

Group:

# 1653

## U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	1.	US 2004/0120959	June 24, 2004	Karl Tryggvason, et al.			October 28, 2003

## FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes      No
	1.	WO 98-32457	7-30-98	PCT			X
	2.	WO 99-31125	6-24-99	PCT			X
	3.	WO 99-26644	6-3-99	PCT			X

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

	4.	Mrug, et al., (1996), "Angiotensin II Facilitates Erythropoietin-mediated proliferation of early erythroid progenitors", Vol: 88, page 646a.
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EXAMINER	DATE CONSIDERED
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